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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,555	08/29/2005	Erik Schwiebert	EL970613375US	7032
23859 7590 08/22/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER PAK, JOHN D	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/542,555

Applicant(s)

SCHWIEBERT ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007 and 22 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 12, 13, 21-23, 37, 38, 41-45, 48-52, 58, 61, 64 and 142-146 is/are pending in the application.
- 4a) Of the above claim(s) 37, 38, 41-45, 48-52, 58, 61 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-3, 12, 13, 21-23 and 142-146 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)            | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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Claims 1-3, 12-13, 21-23, 37-38, 41-45, 48-52, 58, 61, 64 and 142-146 are pending in this application.

Applicant's amendments of 3/1/2007 necessitate the following action taken by the Examiner. Upon applicant's election in the next response, applicant is advised that the next Office action on the merits can be made final because this Office action and the next one will have been necessitated by applicant's amendments.

Lack of unity requirement of 7/11/2006, which withdrew claims 37-38, 41-45, 48-52, 58, 61, 64, must be modified with respect to the amended and new claims.

Withdrawal of said claims is maintained for the reasons stated in the Office action of 7/11/2006, but further restriction is required under 35 U.S.C. 121 and 372 with respect to amended claims 1-3, 12-13, 21-23 and new claims 142-146. Amended claims 1-3, 12-13, 21-23 and new claims 142-146 contain the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to further elect a single invention to which the claims must be restricted.

Group I, claims 1-3, 12-13, 21-23 and 142-146 (all in part), drawn to method of increasing cytosolic  $\text{Ca}^{+2}$  levels in an airway epithelial cell or method of treating an airway disease in a subject comprising contacting cells with  $\text{Zn}^{+2}$  and ATP,  $\alpha$ ,  $\beta$ -methylene ATP, benzoyl benzoyl ATP, ATPyS or AMPPNP.

Group II, claims 1-3, 12-13, 21-23 and 142-146 (all in part), drawn to method of increasing cytosolic  $\text{Ca}^{+2}$  levels in an airway epithelial cell or method of treating an airway disease in a subject comprising contacting cells with  $\text{Zn}^{+2}$  and ivermectin.

Under lack of unity rules, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or

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corresponding special technical features. The expression "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The "contribution over the prior art" is considered with respect to novelty and inventive step. Further, under Markush practice, all alternatives must have a common property AND (i) common structure must be present in all alternatives or (ii) all alternatives must belong to a recognized class of chemical compounds. See PCT Rule 13.1 and 13.2; see also MPEP 1850.

Here, contacting cells with  $\text{Zn}^{+2}$  is the only possible technical feature that could qualify as the same or corresponding "special technical feature" between the two invention groups. However, it has already been established in the original lack of unity requirement of 7/11/2006 that such use of  $\text{Zn}^{+2}$  is not a technical feature that defines a contribution over the prior art – see page 3 of the Office action mailed on 7/11/2006.

Therefore, the inventions of groups I and II are not so linked as to form a general inventive concept. The claims thereby lack a unity of invention as set forth above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Again, applicant is advised that the next Office action after applicant makes an election can be made final because this Office action and the next Office action on the merits will have been necessitated by applicant's amendments of 3/1/2007.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Pak  
Primary Examiner  
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